

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



17 FEB 2022

FDA ADVISORY No. 20220273

TO

ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT

Public Health Warning Against the Purchase and Use of the following Verified Counterfeit Drug Products:

- Ibuprofen / Paracetamol (Alaxan[®] FR) 200 mg / 325 mg Capsule
- 2. Loperamide HCl (Lomotil®) 2 mg Tablet
- 3. Loperamide (Imodium) 2 mg Capsule
- 4. Paracetamol (Biogesic®) 500 mg Tablet
- 5. Carbocisteine (Solmux®) 500 mg Capsule
- 6. D-Alpha Tocopherol (Vitamin E) (Myra e) 400 IU Capsule
- 7. Dextromethorphan HBr / Phenylpropanolamine HCl / Paracetamol (Tuseran® Forte) 15 mg / 25 mg / 325 mg Capsule
- 8. Buclizine HCl / Multivitamins / Minerals (Propan® with Iron) Capsule
- 9. Mefenamic Acid (Gardan®) 500 mg Film-Coated Tablet
- 10. Paracetamol / Caffeine (Rexidol® Forte) 500 mg / 65 mg Tablet
- 11. Ibuprofen (Medicol® Advance) 200 mg Softgel Capsule
- 12. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep® Forte) 10 mg / 2 mg / 500 mg Tablet
- 13. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Tablet



The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit version of the following products:

AUTHENTIC





COUNTERFEIT









Counterfeit - Logo, security mark, knurling, print color and appearance are different from standard.

Figure 1. Comparison between the Authentic and Counterfeit Ibuprofen / Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule (Lot No. 20061688 and 24526670)

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COUNTERFEIT



Figure 2. Comparison between the Authentic and Counterfeit Loperamide HCl (Lomotil®) 2 mg Tablet (Lot No. 20LMT60)

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Figure 3. Comparison between the Authentic and Counterfeit Loperamide (Imodium) 2 mg Capsule (Lot No. 20IMC 0)

AUTHENTIC PARACETAMOL BIOGESIC® 500 mg TABLET PARACETAMOL BIOGESIC® 500 mg TABLET PARACETAMOL UNILAB, Inc. PARACETAMOL BIOGESIC® UNILAB, Inc. UNILAB, Inc. PARACETAMOL PARACETAMOL PARACETAMOL BIOGESIC® 500 mg TABLET BIOGESIC® 500 mg TABLET BIOGESIC® PARAGETAMOL PARACETAMOL UNILAB, Inc. PARACETAMOL PARACETAMOL BIOGESIC BIOGESIC® BIOGESIC® PARACETAMOL UNILAB, Inc. PARAGETAMOL JNILAB, Inc PARACETAMOL BIOGESIC® BIOGESIC® BIOGESIC® 500 mg TABLET UNILAB, Inc. PARACETAMOL UNILAB, Inc. PARAGETAMOL PARAGETAMOL PARACETAMOL BIOGESIC BIOGESIC® BIOGESIC®

COUNTERFEIT



Figure 4. Comparison between the Authentic and Counterfeit Paracetamol (Biogesic®) 500 mg Tablet (Lot No. 20623006)





COUNTERFEIT



Figure 5. Comparison between the Authentic and Counterfeit Carbocisteine (Solmux®) 500 mg Capsule (Lot Nos. U263608 and U053626)





COUNTERFEIT





 $\textbf{Counterfeit} - Logo, \ security \ mark, \ knurling, \ print \ color \ and \ appearance \ are \ different \ from \ standard.$

Figure 6. Comparison between the Authentic and Counterfeit D-Alpha Tocopherol (Vitamin E) (Myra e) 400 IU Capsule (Lot No. 0826 T0)





COUNTERFEIT





Figure 7. Comparison between the Authentic and Counterfeit Dextromethorphan HBr / Phenylpropanolamine HCl / Paracetamol (Tuseran® Forte) 15 mg / 25 mg / 325 mg Capsule (Lot No. U021060)





COUNTERFEIT





Figure 8. Comparison between the Authentic and Counterfeit Buclizine HCl / Multivitamins / Minerals (Propan® with Iron) Capsule (Lot No. 20PRN-15)





COUNTERFEIT





Figure 9. Comparison between the Authentic and Counterfeit Mefenamic Acid (Gardan®) 500 mg Film-Coated Tablet (Lot No. 015)





COUNTERFEIT





Figure 10. Comparison between the Authentic and Counterfeit Paracetamol / Caffeine (Rexidol® Forte) 500 mg / 65 mg Tablet (Lot No. 20028500)





COUNTERFEIT





Figure 11. Comparison between the Authentic and Counterfeit Ibuprofen (Medicol® Advance) 200 mg Softgel Capsule (Lot No. M271298)





COUNTERFEIT







Counterfeit - Logo, security mark, knurling, print color and appearance are different from standard.

Figure 12. Comparison between the Authentic and Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep® Forte) 10 mg / 2 mg /500 mg Tablet (Lot Nos. 20306820 and 23774036)





COUNTERFEIT





Figure 13. Comparison between the Authentic and Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Tablet (Lot No. U264520)

All healthcare professionals and the general public are hereby warned as to the availability of these counterfeit drug products in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of the said counterfeit products with the abovementioned features. The importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009, and Republic Act No. 8203 or the Special Law on Counterfeit Drugs. Anyone found selling the said counterfeit drug products will be penalized.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until it has been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product is registered with the FDA by using the FDA Verification Portal feature accessible at http://verification.fda.gov.ph.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via ereport@fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH and fill out all the required fields

Dissemination of the information to all concerned is requested.

DR. OSCAR G. GUTIERREZ, JR. Officer-in-charge, Director General

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